What is claimed is

1. A method of treating or preventing a clinical symptom of ocular allergy, comprising administering to the eye of a patient an effective amount of alcaftadine, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof.

2. The method of claim 1 wherein the ocular allergy is allergic conjunctivitis.

3. The method of claim 1 wherein said clinical symptom is selected from the group consisting of ocular itching, ocular redness, swelling of the eyelids, chemosis, tearing, and nasal inflammation, nasal congestion, rhinorrhea, nasal pruritis, ear/palate prurtis, and sneezing.

4. The method of claim 1 wherein said clinical symptom is ocular itching

5. The method of claim 1 wherein said clinical symptom is ocular redness.

6. The method of claim 1 further comprising treating or preventing at least two clinical symptoms.

7. The method of claim 6 wherein said at least two clinical symptoms are ocular itching and ocular redness

8. The method of claim 1, further comprising treating or preventing at least three clinical symptoms selected from the group consisting of ocular itching, ocular redness, swelling of the eyelids, chemosis, and tearing

9. The method of claim 1 wherein effective amount is less than about 0.25 mg to greater than about 0.015 mg.

10. The method of claim 1 wherein the effective amount is between about 0.075 mg and about 0.125 mg.

11. The method of claim 1 comprising administering an effective amount of alcaftadine.

12. The method of claim 11 wherein effective amount is between about 0.075 mg and about 0.125 mg.

13. The method of claim 11 wherein the effective amount is between less than about 0.25 mg to greater than about 0.015 mg.

14. The method of claim 11 wherein the clinical symptom is ocular itching.

15. The method of claim 11 wherein the clinical symptom is ocular redness

16. The method of claim 11 further comprising treating or preventing at least two clinical symptoms.

17. The method of claim 16 wherein said at least two clinical symptoms are ocular itching and ocular redness

18. The method of claim 11, further comprising treating or preventing at least three clinical symptoms selected from the group consisting of ocular itching, ocular redness, swelling of the eyelids, chemosis, and tearing

19. A method of treating or preventing a clinical symptom of ocular inflammation, comprising administering to the eye of a patient an effective amount of alcaftadine, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof.

20. The method of claim 19 wherein said clinical symptom is selected from the group consisting of ocular itching, ocular redness, swelling of the eyelids, chemosis, tearing, and nasal inflammation, nasal congestion, rhinorrhea, pruritis (nasal and ear/palate), and sneezing.

21. The method of claim 19 wherein said clinical symptom is ocular itching

22. The method of claim 19 wherein said clinical symptom is ocular redness.

23. The method of claim 19 further comprising treating or preventing at least two clinical symptoms.

24. The method of claim 19, further comprising treating or preventing at least three clinical symptoms selected from the group consisting of ocular itching, ocular redness, swelling of the eyelids, chemosis, and tearing

25. The method of claim 19 wherein effective amount is between less than about 7.1 µg/kg per day and about 3.5 µg/kg per day.

26. The method of claim 19 wherein the effective amount is between less than about 0.25 mg to greater than about 0.015 mg.

27. The method of claim 19 comprising administering an effective amount of alcaftadine.

28. The method of claim 27 wherein effective amount is less than about 0.25 mg to greater than about 0.015 mg.

29. The method of claim 27 wherein the effective amount is between about 0.075 mg and about 0.125 mg.

30. The method of claim 27 wherein the clinical symptom is ocular itching.

31. The method of claim 27 wherein the clinical symptom is ocular redness

32. The method of claim 27 further comprising treating or preventing at least two clinical symptoms.

33. The method of claim 32 wherein said at least two clinical symptoms are ocular itching and ocular redness

34. The method of claim 27, further comprising treating or preventing at least three clinical symptoms selected from the group consisting of ocular itching, ocular redness, swelling of the eyelids, chemosis, and tearing

35. A method of treating or preventing a mechanistic symptom associated with ocular allergy or ocular inflammation comprising administering to the eye of a patient an effective amount of alcaftadine, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof.

36. The method of claim 35 wherein said mechanistic symptom is selected from the group consisting of vascular leakage, a reduction in the integrity of the conjunctival epithelial tight junctions, modulation of the H_4 receptor, and mast cell degradation.

37. The method of claim 35 comprising administering an effective amount of alcaftadine.

38. The method of claim 37 wherein effective amount is less than about 0.25 mg to greater than about 0.015 mg

39. The method of claim 37 wherein the effective amount is between about 0.075 mg and about 0.125 mg.

40. A method of treating or preventing a nasal symptom of ocular allergy, comprising administering to the nose of a patient an effective amount of alcaftadine, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof.

41. The method of claim 40 wherein the nasal symptom of allergy is selected from the group consisting of nasal inflammation, nasal congestion, rhinorrhea, nasal pruritis, and sneezing.

42. The method of claim 41 further comprising treating or preventing at least two nasal symptoms of allergy.

43. The method of claim 41 comprising administering an effective amount of alcaftadine.

44. The method of claim 43 wherein effective amount is less than about 0.25 mg to greater than about 0.015 mg.

45. The method of claim 43 wherein the effective amount is between between about 0.075 mg and about 0.125 mg.

46. A method of treating or preventing a clinical symptom of ocular allergy, comprising administering to the eye of a patient an ophthalmic composition comprising alcaftadine, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof.

47. The method of claim 46 wherein the ocular allergy is allergic conjunctivitis.

48. The method of claim 46 comprising administering an ophthalmic composition comprising alcaftadine.

49. The method of claim 48 wherein the ophthalmic composition comprises from about 0.005% to about 10% by weight of alcaftadine.

50. The method of claim 48 wherein the ophthalmic composition comprises from about 0.2% to about 0.35% by weight of alcaftadine.

51. The method of claim 48 further comprising treating or preventing at least two clinical symptoms of ocular allergy selected from the group consisting of of ocular itching, ocular redness, swelling of the eyelids, chemosis, tearing, and nasal inflammation, nasal congestion, rhinorrhea, nasal pruritis, ear/palate pruritis, and sneezing.

52. An ophthalmic composition comprising alcaftadine, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof.

53. The ophthalmic composition of claim 52, further comprising a vehicle.

54. The ophthalmic composition of claim 52 comprising alcaftadine and a pharmaceutically acceptable vehicle.

55. The ophthalmic composition of claim 52 wherein the ophthalmic composition comprises from about 0.005% to about 10% by weight of alcaftadine.

56. The ophthalmic composition of claim 52 wherein the ophthalmic composition comprises from about 0.2% to about 0.35% by weight of alcaftadine.

57. A kit comprising an ophthalmic composition comprising alcaftadine, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof contained within a container prepared from a pharmaceutically acceptable packaging material.

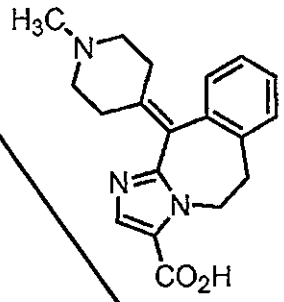
58. The kit of claim 57 wherein the ophthalmic composition is in the form of an ophthalmic solution or suspension.

59. The kit of claim 57 wherein the ophthalmic solution comprises between about 0.1% by weight and about 0.4% by weight of alcaftadine.

60. The kit of claim 59 wherein the pharmaceutically acceptable packaging material is low density polyethylene or high density polyethylene.

61. The kit of claim 59 wherein said container is sterilized with ethylene oxide prior of filing with said ophthalmic solution.

62. A method of treating or preventing a clinical symptom of ocular allergy, comprising administering to the eye of a patient an effective amount of a compound of



Formula II,

its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof.

63. The method of claim 62 wherein the ocular allergy is allergic conjunctivitis.

64. The method of claim 62 wherein said clinical symptom is selected from the group consisting of ocular itching, ocular redness, swelling of the eyelids, chemosis, tearing, and nasal inflammation, nasal congestion, rhinorrhea, nasal pruritis, ear/palate prurtis, and sneezing.

65. The method of claim 62 wherein said clinical symptom is ocular itching

66. The method of claim 62 wherein said clinical symptom is ocular redness.

67. The method of claim 62 further comprising treating or preventing at least two clinical symptoms.

68. The method of claim 67 wherein said at least two clinical symptoms are ocular itching and ocular redness

69. The method of claim 62, further comprising treating or preventing at least three clinical symptoms selected from the group consisting of ocular itching, ocular redness, swelling of the eyelids, chemosis, and tearing

70. The method of claim 62 wherein effective amount is less than about 0.25 mg to greater than about 0.015 mg.

71. The method of claim 62 wherein the effective amount is between about 0.075 mg and about 0.125 mg.

72. The method of claim 62 comprising administering an effective amount of a compound of Formula II.

73. The method of claim 72 wherein effective amount is between about 0.075 mg and about 0.125 mg.

74. The method of claim 72 wherein the effective amount is between less than about 0.25 mg to greater than about 0.015 mg.

75. The method of claim 72 further comprising treating or preventing at least two clinical symptoms.

76. The method of claim 75 wherein said at least two clinical symptoms are ocular itching and ocular redness

77. The method of claim 72, further comprising treating or preventing at least three clinical symptoms selected from the group consisting of ocular itching, ocular redness, swelling of the eyelids, chemosis, and tearing

78. A method of treating or preventing a clinical symptom of ocular inflammation, comprising administering to the eye of a patient an effective amount of a compound of Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof.

79. The method of claim 78 wherein said clinical symptom is selected from the group consisting of ocular itching, ocular redness, swelling of the eyelids, chemosis, tearing, and nasal inflammation, nasal congestion, rhinorrhea, pruritis (nasal and ear/palate), and sneezing.

80. The method of claim 79 further comprising treating or preventing at least two clinical symptoms.

81. The method of claim 79, further comprising treating or preventing at least three clinical symptoms selected from the group consisting of ocular itching, ocular redness, swelling of the eyelids, chemosis, and tearing

82. The method of claim 79 wherein the effective amount is between less than about 0.25 mg to greater than about 0.015 mg.

83. The method of claim 79 comprising administering an effective amount of a compound of Formula II.

84. The method of claim 83 wherein effective amount is less than about 0.25 mg to greater than about 0.015 mg.

85. The method of claim 83 wherein the effective amount is between about 0.075 mg and about 0.125 mg.

86. The method of claim 83 further comprising treating or preventing at least two clinical symptoms.

87. The method of claim 86 wherein said at least two clinical symptoms are ocular itching and ocular redness

88. The method of claim 83, further comprising treating or preventing at least three clinical symptoms selected from the group consisting of ocular itching, ocular redness, swelling of the eyelids, chemosis, and tearing

89 A method of treating or preventing a mechanistic symptom associated with ocular allergy or ocular inflammation comprising administering to the eye of a patient an effective amount of a compound of Formula II, its pharmaceutically acceptable salts, N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof.

90. The method of claim 89 wherein said mechanistic symptom is selected from the group consisting of vascular leakage, a reduction in the integrity of the conjunctival epithelial tight junctions, and mast cell degradation.

91. The method of claim 89 comprising administering an effective amount of a compound of Formula II.

92. The method of claim 91 wherein effective amount is less than about 0.25 mg to greater than about 0.015 mg

93. The method of claim 91 wherein the effective amount is between lbetween about 0.075 mg and about 0.125 mg.

94. A method of treating or preventing a nasal symptom of ocular allergy, comprising administering to the nose of a patient an effective amount of a compound of Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof.

95. The method of claim 94 wherein the nasal symptom of allergy is selected from the group consisting of nasal inflammation, nasal congestion, rhinorrhea, nasal pruritis, and sneezing.

96. The method of claim 94 further comprising treating or preventing at least two nasal symptoms of allergy.

97. The method of claim 94 comprising administering an effective amount of a compound of Formula II.

98. The method of claim 97 wherein effective amount is less than about 0.25 mg to greater than about 0.015 mg.

99. The method of claim 97 wherein the effective amount is between between about 0.075 mg and about 0.125 mg.

100. A method of treating or preventing a clinical symptom of ocular allergy, comprising administering to the eye of a patient an ophthalmic composition comprising a compound of Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof.

101. The method of claim 100 wherein the ocular allergy is allergic conjunctivitis.

102. The method of claim 100 comprising administering an ophthalmic composition comprising a compound of Formula II.

103. The method of claim 100 wherein the ophthalmic composition comprises from about 0.005% to about 10% by weight of a compound of Formula II.

104. The method of claim 100 wherein the ophthalmic composition comprises from about 0.2% to about 0.35% by weight of a compound of Formula II.

105. The method of claim 100 further comprising treating or preventing at least two clinical symptoms of ocular allergy selected from the group consisting of of ocular itching, ocular redness, swelling of the eyelids, chemosis, tearing, and nasal inflammation, nasal congestion, rhinorrhea, nasal pruritis, ear/palate pruritis, and sneezing.

106. A method of treating or preventing a mechanistic symptom of ocular allergy, comprising administering to the eye of a patient an ophthalmic composition comprising a compound of Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof.

107. The method of claim 106 wherein said mechanistic symptom is selected from the group consisting of vascular leakage, a reduction in the integrity of the conjunctival epithelial tight junctions, and mast cell degradation.

108. The method of claim 106 comprising administering an effective amount of a compound of Formula II.

109. The method of claim 106 wherein effective amount is less than about 0.25 mg to greater than about 0.015 mg

110. The method of claim 108 wherein the effective amount is between lbetween about 0.075 mg and about 0.125 mg.

111. A method of treating or preventing a clinical symptom of ocular inflammation, comprising administering to the eye of a patient an ophthalmic composition comprising a compound of Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof.

112. The method of claim 111 wherein the ocular allergy is allergic conjunctivitis.

113. The method of claim 110 comprising administering an ophthalmic composition comprising a compound of Formula II.

114. The method of claim 110 wherein the ophthalmic composition comprises from about 0.005% to about 10% by weight of a compound of Formula II.

115. The method of claim 110 wherein the ophthalmic composition comprises from about 0.2% to about 0.35% by weight of a compound of Formula II.

116. The method of claim 110 further comprising treating or preventing at least two clinical symptoms of ocular allergy selected from the group consisting of ocular itching, ocular redness, swelling of the eyelids, chemosis, tearing, and nasal inflammation, nasal congestion, rhinorrhea, nasal pruritis, ear/palate pruritis, and sneezing.

117. A method of treating or preventing a mechanistic symptom of ocular inflammation, comprising administering to the eye of a patient an ophthalmic composition comprising a compound of Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof.

118. The method of claim 117 wherein said mechanistic symptom is selected from the group consisting of vascular leakage, a reduction in the integrity of the conjunctival epithelial tight junctions, and mast cell degradation.

119. An ophthalmic composition comprising a compound of Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof.

120. The ophthalmic composition of claim 119, further comprising a vehicle.

121. The ophthalmic composition of claim 119 comprising a compound of Formula II and a pharmaceutically acceptable vehicle.

122. The ophthalmic composition of claim 121 wherein the ophthalmic composition comprises from about 0.005% to about 10% by weight of a compound of Formula II.

123. The ophthalmic composition of claim 119 wherein the ophthalmic composition comprises from about 0.2% to about 0.35% by weight of a compound of Formula II.

124. A kit comprising an ophthalmic composition comprising a compound of Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof contained within a container prepared from a pharmaceutically acceptable packaging material.

125. The kit of claim 124 wherein the ophthalmic composition is in the form of an ophthalmic solution or suspension.

126. The kit of claim 124 wherein the ophthalmic solution comprises between about 0.1% by weight and about 0.4% by weight of a compound of Formula II.

127. The kit of claim 124 wherein the pharmaceutically acceptable packaging material is low density polyethylene or high density polyethylene.

128. The kit of claim 127 wherein said container is sterilized with ethylene oxide prior of filing with said ophthalmic solution.

129. A ophthalmic composition comprising alcaftadine, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof for the treatment or prevention of a clinical symptom of ocular allergy.

130. A ophthalmic composition comprising alcaftadine, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof for the treatment or prevention of a clinical symptom of ocular inflammation.

131. A ophthalmic composition comprising alcaftadine, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof for the treatment or prevention of a clinical symptom of allergic conjunctivitis.

132. A ophthalmic composition comprising alcaftadine, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof for the treatment or prevention of a mechanistic symptom of ocular allergy or ocular inflammation.

133. A ophthalmic composition according to any of claims 129 to 32, wherein said treatment or prevention comprises the ocular or nasal administration of said composition.

134. A ophthalmic composition according to claim 133, wherein said treatment or prevention comprises the administration of less than about 0.25 mg to greater than about 0.015mg of alcaftadine.

135. A ophthalmic composition according to claim 133 comprising between about 0.1% by weight and about 0.4% by weight of alcaftadine.

136. A ophthalmic composition comprising a compound of Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof for the treatment or prevention of a clinical symptom of ocular allergy.

137. A ophthalmic composition comprising a compound of Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates,

polymorphs, pro-drugs, or mixtures thereof for the treatment or prevention of a clinical symptom of ocular inflammation.

138. A ophthalmic composition comprising a compound of Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof for the treatment or prevention of a clinical symptom of allergic conjunctivitis.

139. A ophthalmic composition comprising a compound of Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, pro-drugs, or mixtures thereof for the treatment or prevention of a mechanistic symptom of ocular allergy or ocular inflammation.

140. A ophthalmic composition according to any of claims 136 to 39, wherein said treatment or prevention comprises the ocular or nasal administration of said composition.

141. A ophthalmic composition according to claim 140, wherein said treatment or prevention comprises the administration of less than about 0.25 mg to greater than about 0.015mg of a compound of Formula II.

142. A ophthalmic composition according to claim 140 comprising between about 0.1% by weight and about 0.4% by weight of a compound of Formula II.

Claims

1. Alcaftadine, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof, for use in a method of treating or preventing a clinical symptom of ocular allergy, the method comprising administering to the eye of a patient an effective amount of the alcaftadine, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof.

2. Alcaftadine, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof, for use in a method of treating or preventing a clinical symptom of ocular inflammation, the method comprising administering to the eye of a patient an effective amount of the alcaftadine, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof.

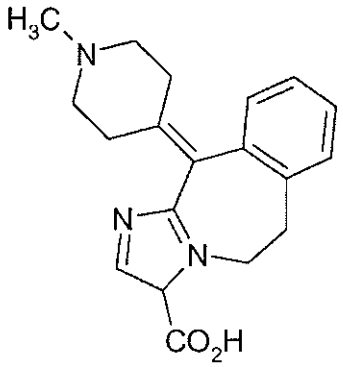
3. Alcaftadine, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof, for use in a method of treating or preventing a mechanistic symptom associated with ocular allergy or ocular inflammation, the method comprising administering to the eye of a patient an effective amount of the alcaftadine, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof.

4. Alcaftadine, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof, for use in a method of treating or preventing a nasal symptom of ocular allergy, the method comprising administering to the nose of a patient an effective amount of the alcaftadine, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof.

5. Alcaftadine, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof, for use in a method of treating or preventing a clinical symptom of ocular allergy, the method comprising

administering to the eye of a patient an ophthalmic composition comprising the alcaftadine, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof.

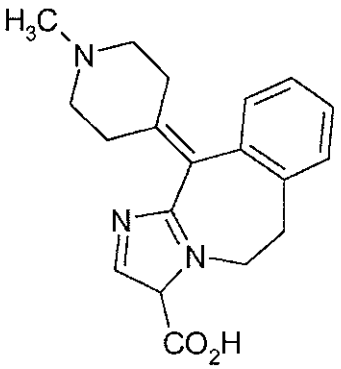
6. A compound of



Formula II,

its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof, for use in a method of treating or preventing a clinical symptom of ocular allergy, the method comprising administering to the eye of a patient an effective amount of the compound of Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof.

7. A compound of

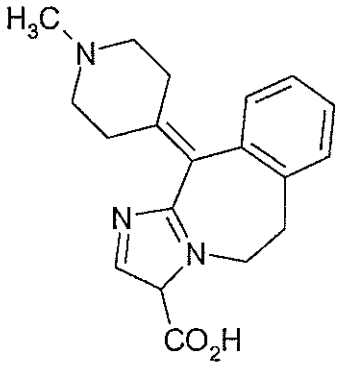


Formula II,

its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof, for use in a method of treating or preventing a clinical symptom of ocular inflammation, the method comprising administering to

the eye of a patient an effective amount of the compound of the Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof.

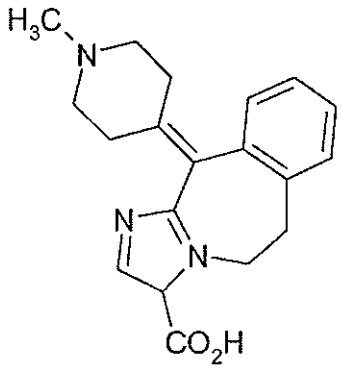
8. A compound of



Formula II,

its pharmaceutically acceptable salts, N-oxides, hydrates, solvates, polymorphs, or mixtures thereof, for use in a method of treating or preventing a mechanistic symptom associated with ocular allergy or ocular inflammation, the method comprising administering to the eye of a patient an effective amount of the compound of Formula II, its pharmaceutically acceptable salts, N-oxides, hydrates, solvates, polymorphs, or mixtures thereof.

9. A compound of

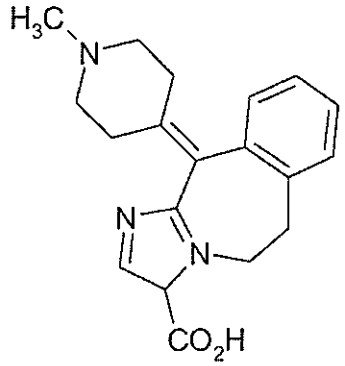


Formula II,

its pharmaceutically acceptable salts, N-oxides, hydrates, solvates, polymorphs, or mixtures thereof, for use in a method of treating or preventing a nasal symptom of ocular allergy, the method comprising administering to the nose of a

patient an effective amount of the compound of the Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof.

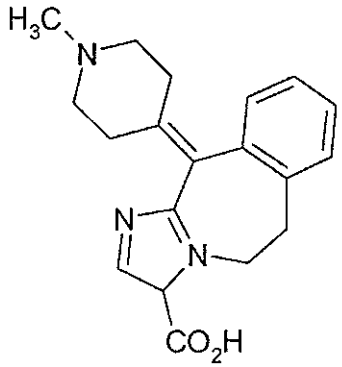
10. A compound of



Formula II,

its pharmaceutically acceptable salts, N-oxides, hydrates, solvates, polymorphs, or mixtures thereof, for use in a method of treating or preventing a clinical symptom of ocular allergy, the method comprising administering to the eye of a patient an ophthalmic composition comprising the compound of Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof.

11. A compound of

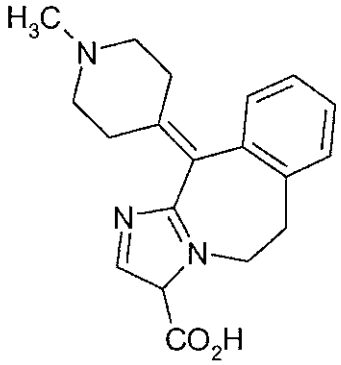


Formula II,

Its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof, for use in a method of treating or preventing a mechanistic symptom of ocular allergy, the method comprising administering to

the eye of a patient an ophthalmic composition comprising the compound of Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof.

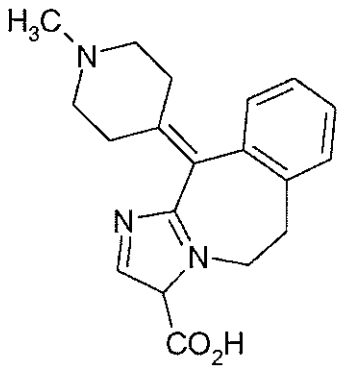
12. A compound of



Formula II,

its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof, for use in a method of treating or preventing a clinical symptom of ocular inflammation, the method comprising administering to the eye of a patient an ophthalmic composition comprising the compound of Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof.

13. A compound of



Formula II,

its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof, for use in a method of treating or preventing a mechanistic symptom of ocular inflammation, the method comprising

administering to the eye of a patient an ophthalmic composition comprising the compound of the Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof.

14. The compound for use as claimed in one of claims 1, 5, 6, 10 or 11 wherein the ocular allergy is allergic conjunctivitis.

15. The compound for use as claimed in one of claims 1, 2, 6 or 7 wherein said clinical symptom is selected from the group consisting of ocular itching, ocular redness, swelling of the eyelids, chemosis, tearing, and nasal inflammation, nasal congestion, rhinorrhea, nasal pruritis, ear/palate pruritis, and sneezing.

16. The compound for use as claimed in one of claims 1, 2 or 6 wherein said clinical symptom is ocular itching.

17. The compound for use as claimed in one of claims 1, 2 or 6 wherein said clinical symptom is ocular redness.

18. The compound for use as claimed in one of claims 1, 2, 6 or 7 further comprising treating or preventing at least two clinical symptoms.

19. The compound for use as claimed claim 18 wherein said at least two clinical symptoms are ocular itching and ocular redness.

20. The compound for use as claimed in one of claims 1, 2, 6 or 7 further comprising treating or preventing at least three clinical symptoms selected from the group consisting of ocular itching, ocular redness, swelling of the eyelids, chemosis, and tearing.

21. The compound for use as claimed in one of claims 1, 2, 6 or 7 wherein effective amount is less than about 0.25 mg to greater than about 0.015 mg.

22. The compound for use as claimed in claim 1 or claim 6 wherein the effective amount is between about 0.075 mg and about 0.125 mg.

23. The compound for use as claimed in one of claims 1, 2 or 3 wherein effective amount is between about 0.075 mg and about 0.125 mg.

24. The compound for use as claimed in one of claims 1, 2 or 3 wherein the effective amount is between less than about 0.25 mg to greater than about 0.015 mg.

25. The compound for use as claimed in one of claims 1, 2 or 3 wherein the clinical symptom is ocular itching.

26. The compound for use as claimed in one of claims 1, 2 or 3 wherein the clinical symptom is ocular redness.

27. The compound for use as claimed in one of claims 1, 2 or 3 further comprising treating or preventing at least two clinical symptoms.

28. The compound for use as claimed in claim 27 wherein said at least two clinical symptoms are ocular itching and ocular redness.

29. The compound for use as claimed in one of claims 1, 2 or 3, further comprising treating or preventing at least three clinical symptoms selected from the group consisting of ocular itching, ocular redness, swelling of the eyelids, chemosis, and tearing.

30. The compound for use as claimed in claim 2 wherein the effective amount is between less than about 7.1 µg/kg per day and about 3.5 µg/kg per day.

31. The compound for use as claimed in claim 3 wherein said mechanistic symptom is selected from the group consisting of vascular leakage, a reduction

in the integrity of the conjunctival epithelial tight junctions, modulation of the H_4 receptor, and mast cell degradation.

32. The compound for use as claimed in claim 4 or claim 9 wherein the nasal symptom of allergy is selected from the group consisting of nasal inflammation, nasal congestion, rhinorrhea, nasal pruritis, and sneezing.

33. The compound for use as claimed in claim 4 or claim 9 further comprising treating or preventing at least two nasal symptoms of allergy.

34. The compound for use as claimed in claim 32 wherein effective amount is less than about 0.25 mg to greater than about 0.015 mg.

35. The compound for use as claimed in claim 32 wherein the effective amount is between about 0.075 mg and about 0.125 mg.

36. The compound for use as claimed in claim 5 wherein the ophthalmic composition comprises from about 0.005% to about 10% by weight of alcaftadine.

37. The compound for use as claimed in claim 5 wherein the ophthalmic composition comprises from about 0.2% to about 0.35% by weight of alcaftadine.

38. The compound for use as claimed in claim 5 further comprising treating or preventing at least two clinical symptoms of ocular allergy selected from the group consisting of ocular itching, ocular redness, swelling of the eyelids, chemosis, tearing, and nasal inflammation, nasal congestion, rhinorrhea, nasal pruritis, ear/palate pruritis, and sneezing.

39. The compound for use as claimed in one of claims 6, 7, 8, 9, or 11 wherein the effective amount is between about 0.075 mg and about 0.125 mg.

40. The compound for use as claimed in one of claims 6, 7, 8, 9, or 11 wherein the effective amount is between less than about 0.25 mg to greater than about 0.015 mg.

41. The compound for use as claimed in one of claims 6, 7, 8, 9, or 11 further comprising treating or preventing at least two clinical symptoms.

42. The compound for use as claimed in claim 41 wherein said at least two clinical symptoms are ocular itching and ocular redness

43. The compound for use as claimed in one of claims 6, 7, 8, 9, or 11, further comprising treating or preventing at least three clinical symptoms selected from the group consisting of ocular itching, ocular redness, swelling of the eyelids, chemosis, and tearing.

44. The compound for use as claimed in one of claims 8, 11 or 13 wherein said mechanistic symptom is selected from the group consisting of vascular leakage, a reduction in the integrity of the conjunctival epithelial tight junctions, and mast cell degradation.

45. The compound for use as claimed in claim 10 or claim 12 wherein the ophthalmic composition comprises from about 0.005% to about 10% by weight of a compound of Formula II.

46. The compound for use as claimed in claim 10 or claim 12 wherein the ophthalmic composition comprises from about 0.2% to about 0.35% by weight of a compound of Formula II.

47. The compound for use as claimed in claim 10 or claim 12 further comprising treating or preventing at least two clinical symptoms of ocular allergy selected from the group consisting of ocular itching, ocular redness, swelling of the eyelids, chemosis, tearing, and nasal inflammation, nasal congestion, rhinorrhea, nasal pruritis, ear/palate pruritis, and sneezing.

48. An ophthalmic composition comprising alcaftadine or a compound of Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof, wherein the ophthalmic composition comprising alcaftadine comprises from about 0.005% to about 10% by weight of alcaftadine.

49. The ophthalmic composition of claim 48, further comprising a vehicle.

50. The ophthalmic composition of claim 48 comprising alcaftadine and a pharmaceutically acceptable vehicle, or a compound of Formula II and a pharmaceutically acceptable vehicle.

51. The ophthalmic composition of claim 48 wherein the ophthalmic composition comprises from about 0.005% to about 0.4% by weight of alcaftadine or of a compound of Formula II.

52. The ophthalmic composition of claim 48 wherein the ophthalmic composition comprises from about 0.2% to about 0.35% by weight of alcaftadine or of a compound of Formula II.

53. A kit comprising an ophthalmic composition comprising alcaftadine or a compound of Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof contained within a container prepared from a pharmaceutically acceptable packaging material, wherein the ophthalmic composition comprising alcaftadine comprises from about 0.005% to about 10% by weight of alcaftadine.

54. The kit of claim 53 wherein the ophthalmic composition is in the form of an ophthalmic solution or suspension.

55. The kit of claim 53 wherein the ophthalmic solution comprises between about 0.1 % by weight and about 0.4% by weight of alcaftadine or of a compound of Formula II .

56. The kit of claim 53 wherein the pharmaceutically acceptable packaging material is low density polyethylene or high density polyethylene.

57. The kit of claim 53 wherein said container is sterilized with ethylene oxide prior of filling with said ophthalmic solution.

58. An ophthalmic composition for use in the treatment or prevention of a clinical symptom of ocular allergy, the ophthalmic composition comprising alcaftadine or a compound of Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof and a vehicle.

59. An ophthalmic composition for use in the treatment or prevention of a clinical symptom of ocular inflammation, the ophthalmic composition comprising alcaftadine or a compound of Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof.

60. An ophthalmic composition for use in the treatment or prevention of a clinical symptom of allergic conjunctivitis, the ophthalmic composition comprising alcaftadine or a compound of Formula II, its pharmaceutically acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof.

61. An ophthalmic composition for use in the treatment or prevention of a mechanistic symptom of ocular inflammation, the ophthalmic composition comprising alcaftadine or a compound of Formula II, its pharmaceutically

acceptable salts, its N-oxides, hydrates, solvates, polymorphs, or mixtures thereof.

62. An ophthalmic composition for use as claimed in any of claims 58 to 61, wherein said treatment or prevention comprises the ocular or nasal administration of said composition.

63. An ophthalmic composition for use as claimed in claim 62, wherein said treatment or prevention comprises the administration of less than about 0.25 mg to greater than about 0.015 mg of alcaftadine or of a compound of Formula II.

64. An ophthalmic composition for use as claimed in claim 62, comprising between about 0.1% by weight and about 0.4% by weight of alcaftadine or of a compound of Formula II.